REMARKS

Applicants intended to continue the prosecution from the point at which the prosecution was previously terminated.

At that time, claims 13-28 were finally rejected under 35 USC § 112, first paragraph, as being broader than the enabling disclosure. In response, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

The Examiner has listed and discussed *individually* the various factors summarized in *In re Wands,* 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), but nowhere does the Examiner *balance* the factors *collectively* to prove that practice of the full scope of the invention would require undue experimentation. Having failed to perform such balancing, Applicants submit that the Examiner has not made out a *prima facie* case of nonenablement.

Further, the Examiner has improperly applied his findings "across-the-board," and not given any consideration to narrower limitations of the dependent claims.

With respect to the first factor, which is the *quantity of experimentation necessary,* the Examiner states that the quantity of experimentation is great, and on the order of many man-years

of effort with little if any reasonable expectation of being able to practice the full scope of the invention. Applicants agree that some experimentation would be required in order to practice the full scope of the invention, but dispute the Examiner's unsupported position that there would be no reasonable expectation of being able to practice the full scope of the invention. In point of fact, the Examiner has not advanced any reason for believing that it should not be possible to practice any aspect of the present invention.

The Examiner has also overlooked the quote in *Wands,* 8 USPQ2d at 1404, from *In re Jackson,* 217 USPQ at 807 (POBA 1982), that:

> "The test [for undue experimentation] is *not merely quantitative,* since a *considerable amount of experimentation is permissible,* if it is merely routine, *or* if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. [Emphasis added.]"

No doubt some experimentation and work would be required to practice the full scope of the invention, possibly even a considerable amount. However, referring again to the quote from *In re Jackson,* even a "considerable" amount of experimentation is permissible so long as the experimentation is routine *or* the specification provides a wealth of guidance.

Not only is any experimentation required here straight-forward, conventional and routine,

but, as will be explained in greater detail below, the specification also provides a reasonable amount of guidance with respect to the direction the experimentation should take. Accordingly, *both* prongs of the *Jackson* "test" are met and, therefore, although some experimentation would be required to practice the full scope of the instant invention, as the Examiner urges, any required experimentation is *not* undue.

With respect to the second and third factors, which are *the amount of direction or guidance presented* and *the presence or absence of working examples,* respectively, the Examiner focuses only on the latter as evidence of the absence of the former. However, the specification provides guidance to persons skilled in the art not only through the working examples, but also through the other descriptive portions of the specification. Thus, for example, there are general teachings on pages 5-9 of all aspects of the invention; a description on pages 9-12, of specific information relating to the use of the invention in connection with the analysis of *nucleic acids;* a description on pages 12-14, of specific information relating to the use of the invention in connection with the analysis of *viruses;* a description on pages 14-16, of specific information relating to the use of the invention in connection with the analysis of *proteins;* a description on pages 16-18, of specific information relating to the use of the invention in connection with the analysis of *bacteria;* and further general teachings on pages 18-19. These teachings are all in addition to the working examples, and provide a wealth of direction or guidance to persons skilled in the art, but are completely ignored in the Examiner's analysis.

With respect to the fourth factor, which is *the nature of the invention,* the Examiner points out that the invention applies to any and all types of macromolecules, but nowhere does the Examiner allege or explain why this finding, even if it were true, supports a finding of undue experimentation. The fact that an invention is broadly applicable does not, in and of itself, suggest that undue experimentation would be required to practice the full scope of the invention.

In connection with this same factor, the Examiner comments that the invention relates to matters of chemistry and physiology, areas that the courts have recognized as being highly unpredictable. However, the present invention does not involve a chemical reaction or any matter of physiology, and, therefore, the Examiner's position here is untenable. Instead, as should be clear from the discussion beginning in the first paragraph on page 5 of the specification and continuing over to page 7, the present invention incorporates a *physical* isolation and concentration of macromolecules, which can then be subjected to any desired analysis. The inventive method involves placing the molecules in a channel, applying a pressure and/or voltage difference across the channel so that the macromolecules migrate to one end or the other, and placing a membrane in the path of such migration so that the macromolecules collect in front of or in the membrane, but do not pass through. Thus, the present invention does *not* operate on unpredictable biological factors, but, rather, on more predictable physical parameters. Consequently, the amount of disclosure required to satisfy the enablement requirement here is not nearly the same as would be required to satisfy the enablement requirement in cases such as

Genentech v. Novo Nordisk A/S, 42 USPQ2d 1001 (Fed. Cir. 1997), cited by the Examiner. However, as discussed above, even though not required, the specification provides a wealth of guidance and direction and working examples.

With respect to the fifth factor, which is *the state of the prior art,* the Examiner finds that the analysis of macromolecules via electrokinetic manipulation was "far from routine," but the Examiner does not cite any literature or provide any other evidence in support of such position.

The Examiner also finds that in order to practice the full scope of the invention persons skilled in the art would have "to resort to the screening of innumerable conditions as well as analyzing scores of reaction conditions with little if any confidence in the applicability of one set of conditions to other macromolecules or devices." Here, again, Applicants disagree with the Examiner's focus only on the quantity of the experimentation, without any consideration given to the fact that all such experimentation is routine, and the specification provides a wealth of guidance and direction, and, also, a number of working examples. Respectfully, the Examiner has not advanced one good reason why a person skilled in the art trying to analyze a given macromolecule using the inventive method should not be able to do so.

The Examiner also finds that the situation is "analogous" to that in *Genentech, supra,* but the present situation is not similar thereto in any significant respect. The invention at issue in

Genentech involved chemical reactions and physiology factors, none of which are involved in the present invention. Also, the prior art there involved previous failures to achieve the invention there, which is not here the case.

Regarding the sixth factor, which is *the relative skill of those in the art,* the Examiner says the ordinary artisan holds a Ph.D. in biochemistry, but offers no explanation how this was calculated. Assuming, for the sake of argument, that the Examiner's assessment is correct, then Applicants point out that this balances against the Examiner's finding of undue experimentation, as less information would be required by such persons to practice the full scope of the invention.

Finally, with respect to the eighth factor, which is *the breadth and scope of the claims,* the Examiner focuses on the nature of the macromolecules, but, again, does not explain why the nature of the molecules would have been expected to make a difference so great as to require undue experimentation. The Examiner also does not treat the narrower dependent claims any differently from the broad independent claims. Claim 14, for example, requires that the macromolecule is a nucleic acid, virus, protein or fungus. Claims 17, 23, and 28 require that the macromolecule is a nucleic acid. Why are these narrower claims subject to this rejection?

Balancing the factors, Applicants submit that the Examiner has not, in fact, made out a *prima facie* case of lack of enablement. Although the claims are broadly drafted, the nature of

the invention does not involve unpredictable chemical reactions or matters of physiology, but, instead, predictable physical factors. Moreover, the level of skill in the art is found by the Examiner to be high. This fact, coupled with the facts that 1) the specification provides a wealth of guidance and direction as to how to practice the full scope of the invention, and, also, provides a number of working examples, and 2) the experimentation required to practice the full scope of the invention has not been shown to involve anything more than routine experimentation, indicates that nothing more than ordinary experimentation would be required to practice the full scope of the invention.

It should also be pointed out that the Examiner has not rejected the claims over any prior art. Accordingly, as a matter of law, Applicants are entitled to broad claims to the broad concept. *See, for example, In re Hogan et al.,* 194 USPQ 527, 537 (CCPA 1977) ("The record reflects no citation of prior art disclosing [the invention,] which may suggest that appellants at least broke new ground in a broad sense. * * * As pioneers, if such they be, they would deserve broad claims to the broad concept.")

In view of the foregoing, Applicants submit that the Examiner would be fully justified to reconsider and to withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is, therefore, earnestly solicited.

Claims 18 and 19 were finally rejected under 35 USC § 112, first paragraph, as being based on an inadequate written description of the invention. In response, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

The Examiner reaches the conclusion that the specification does not provide an adequate written description of the device, nor methods for its manufacture and use, but does not provide any reasons therefor.

The Examiner also says that the device, as claimed, lacks certain essential elements, but does not explain how a failure to claim essential elements, even if true, gives rise to a lack of enablement.

The fact of the matter is that the specification describes exactly what is claimed–a device in the form of a chip module, which device comprises 1-400 capillaries with embedded membrane, wherein if the device comprises multiple capillaries, then the capillaries are arranged side by side. Applicants' position on this point is even supported by the excerpt from *Vas-Cath Inc. v. Mahurkar,* 19 USPQ2d 1111 (Fed. Cir. 1991), which is quoted in the middle of page 6 of the final rejection. According to the quote, "[t]he invention is, for the purposes of the 'written description' inquiry, whatever is now claimed." Inasmuch as the instant specification describes exactly what is presently claimed in claims 18 and 19, these claims cannot be rejected as lacking

adequate written description.

In view of the foregoing, Applicants submit that the Examiner would be fully justified to reconsider and to withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is, therefore, earnestly solicited.

Claims 18 and 19 were finally rejected under 35 USC § 112, second paragraph, as being indefinite for omitting essential elements. In response, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

According to the Examiner, these claims lack certain essential elements, which are listed on page 7 of the Office Action. For support for his position that the claims must recite these elements, the Examiner cites to *Manual of Patent Examining Procedure* ("MPEP") § 2172.01.

MPEP § 2172.01 actually provides as follows:

> "A claim which omits matter *disclosed to be essential to the invention as described in the specification or in other statements of record* may be rejected under 35 U.S.C. § 112, *first paragraph,* as not enabling. Such essential matter may include missing elements, steps or necessary structural cooperative relationships of elements *described by the applicant(s) as necessary to practice the*

invention.

> "In addition, a claim which fails to interrelate essential elements of the invention *as defined by applicant(s) in the specification* may be rejected under 35 U.S.C. § 112, *second paragraph,* for failure to point out and distinctly claim the invention. [All emphasis added and citations omitted.]"

It should be clear that there are a number of problems with this rejection. First, according to this section of the MPEP, a rejection for failure to recite essential matter arises under 35 USC § 112, first paragraph, *not* second paragraph. Accordingly, this rejection is without a proper statutory basis.

Second, a rejection for failure to recite essential matter only arises where Applicants have indicated in the specification or in arguments to the Patent Office that the missing matter is, in fact, essential. As the proponent of this rejection, the burden was on the Examiner to make out a *prima facie* case of unpatentability. The Examiner has not shown where in the specification or in arguments made to the Patent Office Applicants have declared each of the allegedly omitted elements to be essential.

Further on this point, Applicants have amended the preambles of claims 18 and 24 to make clear that the claimed devices are "for use in performing the method of claim 13," which

means that the device could be, for example, a chip module in a larger device adapted to perform the method.

In view of the foregoing, Applicants submit that the Examiner would be fully justified to reconsider and to withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is, therefore, earnestly solicited.

A clean copy of claims 18 and 24 is presented above. A mark-up showing the changes that have been made to these claims using brackets and underlining is attached.

For the record, Applicants emphasize that although these claims were amended, and, therefore, might be argued to have been amended for a reason substantially related to patentability, a fair reading of the amended claims will reveal that the departures from the previous claims were for clarification purposes only, and that Applicants did not narrow the claims in any material respect. Therefore, Applicants submit that the amended claims are entitled to the full range of equivalents.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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MARK-UP SHOWING THE CHANGES MADE IN THE PREVIOUS CLAIM TO YIELD THE CLAIM AS AMENDED ABOVE

– –18. (Once Amended) A device [adapted to perform] **for use in performing** the method of claim 13, said device being in the form of a chip module, said device comprising 1-400 capillaries with embedded membrane, wherein if the device comprises multiple capillaries, the multiple capillaries are arranged side by side. – –

– –24. (Once Amended) A device [adapted to perform] **for use in performing** the method of claim 13, said device comprising a channel adapted to analyze salt-containing samples with embedded membrane. – –